

II. Remarks

Claims 1, 9 and 41 have been amended herein without prejudice to the scope of coverage of the present case or the Applicants' ability to file a broader claim in a further continuation application. Support for the amendment can be found in the specification as originally filed, e.g., at page 16, lines 31, to page 17, line 15, and in original claim 9.

Claims 2, 4-7, 11, 28, 33-34 were previously cancelled without prejudice.

Claims 1, 3, 8-10, 12-27, 29-32, and 35-45 are currently pending.

Applicants respectfully submit that no new matter has been added by virtue of this amendment.

A. Claim Rejection Under 35 U.S.C. § 112, first paragraph

In the Office Action, claims 1, 3, 8-10, 12-27, 29-32, and 35-45 were rejected under 35 U.S.C. § 112, first paragraph, allegedly for the lack of written description for the terms "opioid agonist" and "opioid antagonist," for the reasons set forth on page 2 of the Office Action of February 2, 2007.

In response, Applicants submit that independent claims 1 and 41 have been amended without prejudice to recite that (i) an opioid agonist is "selected from the group consisting of alfentanil, allylprodine, alphaprodine, anileridine, benzylmorphine, bezitramide, buprenorphine, butorphanol, clonitazene, codeine, desomorphine, dextromoramide, dezocine, diampromide, diamorphine, dihydrocodeine, dihydromorphine, dimenoxadol, dimepheptanol, dimethylthiambutene, dioxaphetyl butyrate, dipipanone, eptazocine, ethoheptazine, ethylmethylthiambutene, ethylmorphine, etonitazene, fentanyl, heroin, hydrocodone,

hydromorphone, hydroxypethidine, isomethadone, ketobemidone, levorphanol, levophenacetylmorphan, lofentanil, meperidine, meptazinol, metazocine, methadone, metopon, morphine, myrophine, narceine, nicomorphine, norlevorphanol, normethadone, nalorphine, nalbuphene, normorphine, norpipanone, opium, oxycodone, oxymorphone, papaveretum, pentazocine, phenadoxone, phenomorphan, phenazocine, phenoperidine, piminodine, piritramide, propheptazine, promedol, properidine, propoxyphene, sufentanil, tilidine, tramadol, mixtures of any of the foregoing, and salts of any of the foregoing”; and (ii) that an opioid antagonist is “selected from the group consisting of naltrexone, naloxone, nalmephene, cyclazocine, levallorphan, pharmaceutically acceptable salts thereof and mixtures thereof.”

Support for this amendment can be found in the specification as originally filed, e.g., at page 16, lines 31, to page 17, line 15, and in original claim 9.

Accordingly, withdrawal of the rejection is respectfully requested.

B. Double Patenting Rejection

In the Office Action, claims 1, 3, 8-10, 12-27, 29-31, and 41-44 were rejected based on the judicially created doctrine of nonstatutory double patenting over the claims 1-55 of the parent case, U.S. Patent No. 6,375,957 to Kaiko et al. (hereinafter “the parent case”).

In response, Applicants submit herewith a terminal disclaimer over U.S. Patent No. 6,375,957 to Kaiko et al.

Applicants note that the filing of the terminal disclaimer is not meant to be an admission of the propriety of the rejection by the Examiner. In this regard, the Examiner’s attention is directed to *Quad Environmental Technologies Corp. v. Union Sanitary District*, 946 F.2d 870, 20 USPQ2d 1392 (Fed. Cir. 1991), which states that the “filing of a terminal disclaimer simply

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serves the statutory function of removing the rejection of double patenting, and raises neither a presumption nor estoppel on the merits of the rejection." *Quad Environmental Technologies Corp. v. Union Sanitary District*, 946 F.2d 870, 20 USPQ2d 1392 (Fed. Cir. 1991). The Examiner's attention is further directed to the Manual of Patent Examining Procedure, Section 804.02., which states that "[t]he filing of a terminal disclaimer to obviate a rejection based on nonstatutory double patenting is not an admission of the propriety of the rejection."

Applicants respectfully request withdrawal of the double patenting rejection.

III. Conclusion

An early and favorable action on the merits is earnestly solicited. According to currently recommended Patent Office policy, the Examiner is specifically authorized to contact the undersigned in the event that a telephonic interview will advance the prosecution of this application.

Respectfully submitted,
DAVIDSON, DAVIDSON & KAPPEL, LLC

By: 
Oleg Ioselevich
Reg. No. 56,963

Davidson, Davidson & Kappel, LLC
485 Seventh Avenue, 14th Floor
New York, New York 10018
(212) 736-1940